Supreme Court, U.S.
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No.

IN THE
Supreme Court of the United States

Lone Star Bakery, Inc., Petitioner

v.

United States of America, Respondent

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

I. Whether the Fifth Circuit Court of Appeals was incorrect in ruling that Lone Star Bakery failed, as a matter of law, to establish proximate cause when reasonable minds could draw conflicting inferences from the facts.

II. Whether the District Court erred in finding that Lone Star Bakery failed, as a matter of law, to establish a duty of care under Texas state law; the Fifth Circuit Court of Appeals found the causation issue dispositive; therefore, it did not address the issue of duty.

RULE 29.6

Petitioner, pursuant to Rule 29.6, states that it is a privately held company. There is no publicly held corporation that owns more than 10% of its stock.

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OPINIONS BELOW

The unpublished opinion of the United States District Court for the Western District of Texas, San Antonio Division, in *Lone Star Bakery, Inc. v. The United States of America* (Docket No. SA-05-CA-11-H), decided March 6, 2009, granting Respondent summary judgment, is set forth in the Appendix hereto (App.A).

The unpublished opinion of the United States Court of Appeals for the Fifth Circuit in *Lone Star Bakery, Inc. v. The United States of America* (Docket No. 09-50374), filed on November 17, 2009, affirming the District Court's granting of Respondent's summary judgment, is set forth in the Appendix hereto (App. B).

The United States Court of Appeals for the Fifth Circuit's Order denying Lone Star Bakery, Inc.'s Motion for Rehearing, filed on January 12, 2010, is set forth in the Appendix hereto (App. C).

JURISDICTION

The decision of the United States Court of Appeals for the Fifth Circuit, affirming the decision of the district court's order granting summary judgment, was handed down on November 17, 2009. A timely petition for rehearing was denied on January 12, 2010. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT PROVISIONS INVOLVED

Federal Tort Claims Act, 28 U.S.C. § 1346(b):

"Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone and the District Court of the Virgin Islands, shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

Chapter 1 of the FDA's Bacteriological Analytical Manual

"The adequacy and condition of the sample or specimen received for examination are of primary importance. If samples are improperly collected and mishandled or are not representative of the sampled lot, the laboratory results will be meaningless."

"There can be no compromise in the use of sterile sampling equipment and the use of aseptic technique."

"If plastic bags were used for sampling, be certain that twist wires did not puncture surrounding bags. Any cross-contamination resulting from one or more of above defects would invalidate the sample, and the collecting district should be notified."

Chapter 4 of the FDA Office of Regulatory Affairs, USFDA Investigations Manual

Subchapter 405.1
"To be useful, an Official Sample must be: handled, identified, and sealed in such a manner as to maintain its integrity as evidence, with a clear record of its chain of custody."

Subchapter 426
"Aseptic sampling is a sampling technique used to assure you are not increasing the microbial load of a product sample by your sampling method. The use of sterile sampling implements and containers and a prescribed sampling method defines aseptic sampling. This method of sampling also assures that you are not contaminating what remains in the container from which you sample."

Subchapter 426.1
"If it is necessary to open containers, draw the sample and submit it under conditions, which will

prevent multiplication or undue reduction of the bacterial population. Follow the basic principles of aseptic sampling technique. Take steps to minimize

exposure of product, sampling equipment, and the interior of sampling containers to the environment."

"Sterilized Equipment -- Use only sterilized equipment and containers."

21 CFR – 7.45 (FDA Requested Recall)

"The Commissioner of Food and Drugs or his designee under 5.20 of this chapter may request a firm to initiate a recall when the following determinations have been made:

1. That a product that has been distributed presents a risk of illness or injury or gross consumer deception.
2. That the firm has not initiated a recall of the product.
3. That an agency action is necessary to protect the public health and welfare."

STATEMENT OF THE CASE

Petitioner, Lone Star Bakery, Inc. asserts in this case that the FDA negligently collected a sample of its biscuit product, which resulted in a false positive finding. There is sufficient evidence to raise a fact issue as to whether the FDA's actions

were the proximate cause of the false positive finding. The FDA's negligence resulted in substantial monetary damages to Lone Star Bakery, Inc.

The FDA conducted an investigation at MarketFare Foods (a sandwich assembler) in Phoenix, Arizona upon learning that particular biscuit sandwiches assembled at MarketFare may be contaminated with *Listeria Monocytogenes*, a fatal bateria. Lone Star Bakery, Inc. is the manufacturer of the biscuit component of the sandwiches. The FDA collected various components of the biscuit sandwiches, i.e. biscuit, cheese, sausage, egg. The FDA reported a positive finding of *LM* in the biscuit component and the sandwich component as a whole. The FDA requested MarketFare recall the biscuit sandwiches, and MarketFare issued a recall on April 5, 2002.

The gravamen of Lone Star Bakery's claim is that the FDA employee who collected the biscuit component sample at MarketFare was negligent in the performance of his duties, and his negligence caused a false positive finding of *LM*. The FDA is mandated to follow certain procedures throughout its collection process to ensure that the integrity of the sample it collects and test is not compromised. *See Chapter 1 of the FDA's Bacteriological Analytical Manual and Chapter 4 of the FDA Office of Regulatory Affairs, USFDA Investigations Manual.*

There is sufficient evidence to draw the inference that the FDA's failure to follow its mandated rules, regulations, and directives resulted in the contamination of the biscuit component. The FDA employee that collected the biscuit component at MarketFare testified that it is possible that he may have contaminated the biscuit. The FDA employee testified that he did not place the biscuit samples in a sterile container. The FDA employee testified that when he handled the perforated pillowpak of biscuits, he did not know the pillowpak was perforated (tiny holes in the pillowpaks are necessary because the bags are heat-shrink wrapped). The FDA testified that the documents did not establish a chain of custody. Lone Star Bakery's expert testified that the FDA's failure to follow its mandated rules and regulations concerning aseptic handling and other collection processes of food sampling render any results that flow therefrom meaningless. The FDA, however, reported a positive finding of *LM*, which false positive finding caused Lone Star Bakery the damages to which it seeks herein. Lone Star Bakery has established a fact issue regarding proximate cause.

The FDA never requested that Lone Star Bakery recall any of the millions of biscuits it manufactured and distributed to customers during the same relevant time period, which is additional evidence that infers the FDA knew it caused the

positive finding of *LM* in the biscuit component it collected at MarketFare. If the FDA believed Lone Star Bakery was the source of *LM*, and knowing there were millions of biscuits distributed to Popeyes', Whataburger, and Denny's during this same time period, the FDA would be required to issue a recall, or at the very least request that Lone Star Bakery issue a voluntary recall because *LM* is a fatal bacteria. 21 CRF § 7.45. The FDA made no such request. This evidence raises an inference that the FDA was the source of the contamination from the biscuit sample it collected at MarketFare in Phoenix. To believe otherwise would be to suggest the FDA believed there were millions of biscuits distributed throughout the United States potentially contaminated with a fatal bacteria, and it chose not to request or mandate a recall. As we say in Texas, that dog don't hunt!

The United States District Court for the Western District of Texas granted the FDA's Summary Judgment finding that Lone Star Bakery had failed, as a matter of law, to establish duty and causation. The United States Fifth Circuit Court of Appeals did not address the duty issue; rather it found the causation issue to be dispositive and affirmed the District Court's Summary Judgment.

REASONS FOR GRANTING THE WRIT

As to the first question presented for review, the Fifth Circuit Court of Appeals disregarded

settled Texas law in holding that Lone Star Bakery failed as a matter of law to establish proximate cause.

The Texas Supreme Court has held that causation is a fact issue if more than one inference can be drawn from the facts. *Garza v. Alviar*, 395 S.W.2d 821, 823 (Texas 1965). It is for a jury to decide whether the FDA's admitted failure to use aseptic means caused the contamination in the biscuit sample it collected at MarketFare because reasonable minds could draw conflicting inferences from the evidence established by Lone Star Bakery. *Collora n. Navarro,*, 574 S.W.2d 65, 68 (Texas. 1978); *Peerenboom v. HSP*, 910 S.W.2d 156 (Tex. App. – Waco 1995, no writ). Further, a reasonable jury could conclude that the FDA contaminated the biscuit sample collected at MarketFare, which would explain why the FDA did not recall the millions of biscuits manufactured by Lone Star Bakery and distributed to Popeyes, Whataburger, and Dennys during this same relevant time period. *McGuire v. Overton Memorial Hosp.*, 514 S.W. 79, 85 (Tex. Civ. App. – Tyler 1974, writ ref'd n.r.e per curiam). Lone Star Bakery established more than one inference of causation; thus, the law in Texas requires that the issue must then go to the jury to weigh the credibility of the witnesses and render a finding. *Potter v. Anthony Crane Rental of Texas, Inc.*, 896 S.W.2d 845, 851 (Tex. App. – Beaumont 1995, writ denied).

The Fifth Circuit Court of Appeals erred in finding that the FDA's testimony permits an inference of breach, but it fails to raise a fact issue as to whether the FDA's conduct caused the biscuit sample to test falsely positive. Lone Star Bakery asserts the FDA caused the biscuit to test positive and the FDA asserts Lone Star Bakery was the source. Who caused the *LM* in the biscuit component is the ultimate fact issue that should be decided by a jury. The FDA handled the biscuit component that tested positive, and has admitted it did not place the sample in a sterile container. When it is established that a food sample is not collected aseptically, and there is a finding of contamination, the source of the contamination is unknown, which is why results are rendered invalid. In this case, the biscuit component was admittedly not collected aseptically, and admittedly, no chain of custody can be established by the documents. Yet, the FDA reported a finding as if it were valid and meaningful. Lone Star Bakery has established by the facts that more than a mere possibility exist that the FDA caused the contamination; the facts establish a probability, particularly when all inferences are indulged in favor of Lone Star Bakery. *Martin v. Durden*, 965 S.W.2d 562, 564 (Tex. App. – Houston [14th Dist.] 1997). The FDA did not use aseptic collection techniques or establish a documented chain of custody; thus, no one can discern with absolute certainty the source of contamination. You can, however, review the facts, weigh the credibility of the witnesses, and make

inferences as to causation and let reasonable minds decide the source of contamination. In our case, the FDA admits that its conduct may have caused the contamination in the biscuit component. In our case, the FDA admits that it did not place the biscuit component in a sterile container. In our case, the FDA admits that the documents do not establish a chain of custody. In our case, the FDA admits that it did not get a single positive finding of *LM* in any biscuit sample it collected from Lone Star Bakery's facility. In our case, the FDA admits that it did not request a recall of a single biscuit from the market. In our case, Lone Star Bakery's expert testified that the FDA failed to follow its mandated rules and regulations during the collection process at MarketFare, and those failures rendered any results that flowed therefrom meaningless and invalid. Lone Star Bakery did not just offer "pieces of evidence that pertain to the issue of proximate causation," as stated by the Fifth Circuit, Lone Star Bakery offered evidence that allows a reasonable jury to find that the FDA caused the contamination. In Texas, the question of proximate cause is a factual issue and only in extraordinary cases should this issue be taken from a jury. *Tex. Dep't of Transp. v. Olson*, 980 S.W. 890, 893 (Tex. App. – Fort Worth 1998, no pet.); *Springall v. Fredericksburg Hosp. and Clinic*, 225 S.W.2d 232, 234 (Tex. Civ. App. – San Antonio 1949, no writ). There is nothing extraordinary about this case that warrants depriving Lone Star Bakery of its right to present these established fact to the factfinder.

As to the second question presented for review, the Court below did not rule on the District Court's finding that Lone Star Bakery failed to establish a duty under Texas law. The Fifth Circuit Court of Appeals found the issue of causation dispositive, so it did not address the issue of duty.

The District Court erred in finding that the FDA did not owe a duty of care to Lone Star Bakery under Texas law.

The Fifth Circuit Court of Appeals has held that the government's failure to follow its regulations and protocols does not give rise to an action under the Federal Tort Claims Act **unless** the offending federal employee would owe a duty under state law if it were a private person or entity. *Johnson v. Sawyer,* 47 F.3d 716, 728 (5th Cir. 1995) (en banc). A private laboratory collecting and testing product for Lone Star Bakery owes a duty of care to Lone Star Bakery. The FDA collected and tested the biscuit component manufactured by Lone Star Bakery, and reported a false positive. Neither the Fifth Circuit Court of Appeals nor the Texas Supreme Court has held that no duty exists between an employer and the lab it retains. *Willis v. Roche Biomedical Laboratories, Inc.,* 61 F.3d 313, 316 (5th Cir. 1995) (case focused on relationship between employee and lab; rather than relationship between employer and laboratory); *SmithKline Beecham Corp. v. Doe,* 903 S.W.2d 347, 351 (Tex. 1995)

(case focused on whether private lab had a duty to warn testee that poppy seeds could effect test results).

In our case, the FDA's failure to follow its rules, regulations, and guidelines does give rise to an action under the FTCA because if the FDA were a private entity, it would, under state law, owe a duty of care to Lone Star Bakery. This position is not inconsistent with the Fifth Circuit Court of Appeals decisions. *See Quijano v. United States,* 325 F.3d 564, 568 (5th Cir. 2003); *Johnson v. Sawyer,* 47 F.3d 716, 728 (5th Cir. 1995) (federal regulations may be evidence of negligence if duty exist under state law.) The FDA does have a duty to exercise reasonable care in performing its operational tasks, and in this case, fact issues exist as to whether those tasks were performed while exercising due care.

The Texas Supreme Court has held that in determining whether a legal duty exist, you must consider several interrelated factors, such as the risk, foreseeability, likelihood of injury weighed against the social utility of the actor's conduct, the magnitude of the burden of guarding against the injury, and the consequences of placing the burden on the defendant. *Greater Houston Transp. Co. v. Phillips,* 801 S.W.2d 53, 525. Considering all these factors, the FDA owed a duty of care to Lone Star Bakery.

CONCLUSION

Petitioner respectfully requests the issuance of a writ of certiorari to the United States Court of Appeals for the Fifth Circuit, and ultimately, to vacate that judgment and remand the matter for trial, and provide petitioner with such other fair and just relief to which it is entitled in this case.

Respectfully submitted,

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APPENDIX A – ORDER REGARDING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT FILED MARCH 6, 2009

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS

No. SA-05-CA-11-H

LONE STAR BAKERY, INC.,

Plaintiff,

v.

UNITED STATE OF AMERICA,

Defendant.

ORDER REGARDING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

This is a hard case, but not a difficult one. Plaintiff Lone Star Bakery, Inc. operates a commercial bakery in China Grove, Texas. It brings this civil action for damages against the United States of America under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 et seq. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1346 (b). In its amended complaint, the Plaintiff alleges that it suffered injury as a proximate result of the negligence of the Food and Drug Administration in

connection with the recall of one of its products in 2002. On November 7, 2008, the Defendant filed a motion to dismiss. Since the Defendant's motion relies in part on matters outside the pleadings, it must be treated as a motion for summary judgment under Rule 56, Federal Rules of Civil Procedure.

The following facts are established by the summary judgment evidence: on or about March 1, 2002, a customer of the Save-A-Lot store in Daytona Beach, Florida purchased an egg and sausage sandwich on a cheese biscuit. After eating the sandwich, the customer had a stomach ache. The matter was reported to the Florida Department of Agriculture and Consumer Services, which dispatched an inspector to the Save-A-Lot store. The state inspector collected five of the egg, sausage, and cheese biscuit sandwiches and took them to the State's laboratory for testing. Two of those sandwiches tested positive for a bacterium called *Listeria monocytogenes*. The distributor of the sandwiches, MarketFare of Phoenix, Arizona, was notified of these findings. On March 22, 2002, MarketFare issued a voluntary recall of the product.

On or about March 20, 2002, the Florida agency also passed on its findings to the Orlando office of the Food and Drug Administration. On March 21, 2002, the FDA sent inspectors to the MarketFare plant in Phoenix to collect additional samples for laboratory testing. This time, the FDA inspectors collected samples of the component parts as well as samples of the finished product. The samples thus collected were sent to the FDA's

regional laboratory in Los Angeles, California for further testing. A few days later the FDA notified MarketFare that both the finished sandwich and the biscuit component had tested "presumptive positive" for *Listeria monocytogenes*. In April 2002, MarketFare issued another voluntary recall of this product. MarketFare also informed Southland Corporation (7-Eleven Stores) of the positive test results. According to the Plaintiff, Southland decided to discontinue use of all biscuits from Plaintiff's bakery, and terminated a long-standing business relationship with the Plaintiff. The Plaintiff contends that these events proximately caused irreparable harm to its business, resulting in losses of more than two million dollars.

In April 2002, FDA inspectors arrived at the Plaintiff's China Grove bakery to conduct an inspection. In the course of that inspection, FDA personnel observed perforations in the "shrink wrap" used by the Plaintiff to seal the biscuits before they were shipped to MarketFare in Phoenix. It is the Plaintiff's contention that the FDA inspectors' lack of awareness of the perforations in the shrink wrap when the products were tested in March 2002 compromised the test results, and could have caused an innocent bakery (Lone Star) to be blamed for the presence of *Listeria* in the sandwiches. The Plaintiff asserts that the FDA was negligent in failing to follow its own regulations and procedures in collecting and testing samples, and that such negligence was the proximate cause of severe financial harm to the Plaintiff.

The Government is liable to a claimant under the Federal Tort Claims Act only if a private party under the same or similar circumstances would be liable under the law of the place where the tortious act or omission occurred. 28 U.S.C. §§ 1346 (b); 2674. In the instant case, the Plaintiff has the burden of proving that a private testing laboratory would be held liable for negligence under Texas law on the basis of the facts presented in this case. In this connection, the Plaintiff must do more than show that the federal agency did not follow its own regulations and procedures. *Quijano v. United States*, 325 F.3d 564, 568 (5th Cir. 2003); *Johnson v. Sawyer*, 47 F.3d 716, 727-28 (5th Cir. 1995) (en banc); *Tindall v. United States*, 901 F.2d 53, 56 n. 8 (5th Cir. 1990); *United States v. Smith*, 324 F.2d 622, 624-25 (5th Cir. 1963). The standard of care applicable to a private entity under state law is not determined by the regulations of a federal agency, which may be more strict than state law requires. *Quijano*, 325 F.3d at 568. The Plaintiff's evidence fails to establish a standard of care applicable to a private testing laboratory in Texas. Instead, its evidence, including expert opinion evidence, focuses almost exclusively on the alleged failure of the Food and Drug Administration to follow its own regulations, procedures, and protocols to the letter. This is insufficient to raise a genuine fact issue which would preclude summary judgment.

The Plaintiff also has the burden of proving that the alleged negligence of the Food and Drug Administration was a proximate cause of its

loss. The summary judgment proof indicates that *Listeria* was present in at least some of the cheese biscuit sandwich samples tested in both state and federal laboratories in March 2002. Although seven years have gone by since those events occurred, and more than four years since the Plaintiff's complaint was filed in January 2005, the Plaintiff has come forward with no evidence that employees of the Food and Drug Administration somehow contaminated the cheese biscuit sandwiches with *Listeria.* The scenario was that state and federal laboratories detected the presence of *Listeria* in the product; MarketFare was notified; MarketFare issued a recall for the product; MarketFare notified Southland Corporation; and Southland chose to cancel orders for bakery products manufactured by Lone Star, resulting in injury to the Plaintiff. However, in spite of the passage of years, the Plaintiff has been unable to develop evidence which would raise a genuine fact issue as to whether any act or omission on the part of the Food and Drug Administration was a proximate cause of its injury.

In summary, there is no genuine issue of material fact, and the Defendant is entitled to judgment in its favor as a matter of law.

IT IS THEREFORE ORDERED that the Defendant's motion, treated as a motion for summary judgment under Rule 56, be, and it is hereby, GRANTED.

IT IS FURTHER ORDERED that judgment be, and it is hereby, entered in favor of the

Defendant, and that the Plaintiff take nothing by its suit.

IT IS FURTHER ORDERED that the Plaintiff pay the costs of suit herein incurred, for which let execution issue.

SIGNED AND ENTERED this 5th day of March, 2009.

/s/
HARRY LEE HUDSPETH
Sen. United States District Judge

APPENDIX B – OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT DECIDED ON NOVEMBER 17, 2009

No. 09-50374

LONE STAR BAKERY, INC.,

Plaintiff - Appellant,

v.

UNITED STATE OF AMERICA,

Defendant - Appellee.

Appeal from the United States District Court for the Western District of Texas
No. 5:05-CV-11 – Harry Lee Hudspeth, *Judge*

Decided November 17, 2009

Before King, Stewart, and Haynes, Circuit Judges.

PER CURIAM:

Lone Star Bakery brought a negligence claim against the government under the Federal Tort Claims Act, alleging that Food and Drug Administration agents negligently caused an

erroneous report of dangerous bacteria in its products. The district court granted summary judgment to the government, finding that Lone Star had failed to raise fact issues on the elements of duty and causation. Because we agree that Lone Star has failed to raise a fact issue on causation, we affirm.

I. FACTUAL AND PROCEDURAL BACKGROUND

Lone Star Bakery, Inc. is a commercial baker that makes biscuits at a plant in China Grove, Texas. Until 2002, Lone Star had sold biscuits to Southland Corporation, the owner of 7-Eleven convenience stores. Under that arrangement, Lone Star delivered biscuits to Phoenix, Arizona, where MarketFare Foods, Inc. assembled them into completed sandwiches for delivery to convenience stores; MarketFare purchased other ingredients, such as egg and cheese, from different vendors. The termination of Lone Star's arrangement with Southland prompted the lawsuit at issue.

On March 1, 2002, the Florida Department of Agriculture and Consumer Services received a consumer complaint of gastrointestinal distress. The complaint alleged that the stomachache was caused by consumption of a sausage, egg, and cheese biscuit sandwich purchased from a convenience store in Daytona Beach, Florida. An inspector collected five sample sandwiches from the store, two of which tested positive for *Listeria*

monocytogenes, a harmful and potentially fatal bacterium. The Florida agency alerted MarketFare and the United States Food and Drug Administration (FDA).

The FDA began its investigation at MarketFare's Phoenix assembly plant. Two inspectors collected the individual components and shipped them to an FDA laboratory in California. There, the individual components were tested. On April 5, 2002, a representative from the FDA informed MarketFare that the biscuit component and the finished sandwich had both tested presumptive positive for *Listeria monocytogenes*. That same day, MarketFare issued a recall of the sandwiches, and Southland terminated its business relationship with Lone Star.

On April 9, the FDA conducted an inspection at Lone Star's China Grove plant. FDA workers observed perforations in the plastic packaging used to seal the biscuits before they were shipped to MarketFare. Lone Star was informed on April 25 that the facility and biscuits tested negative for *Listeria monocytogenes*; a written report to this effect was issued on April 30. During this time, the FDA did not order a recall of any Lone Star biscuits.

Lone Star filed an administrative claim with the FDA on August 1, 2003, claiming over $2.9 million in damages. After waiting the requisite six months under 28 U.S.C. § 2675(a), Lone Star filed suit in federal district court under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 *et seq.* Lone Star's amended complaint alleged that the FDA was

negligent in its collection, testing, and reporting of the biscuit samples manufactured by Lone Star.

The government moved to dismiss Lone Star's complaint under Federal Rules of Civil Procedure 12(b)(6) for failure to state a claim upon which relief could be granted. Lone Star filed a memorandum in opposition to the motion and attached a partial transcript of the deposition of Bruce Benware, one of the FDA representatives who collected sandwich components at MarketFare's Phoenix plant. The government filed a reply, attaching the reports of both parties' experts. Because matters outside the pleadings were presented, the district court treated the government's motion as one for summary judgment under Rule 56. *See* Fed. R. Civ. P. 12(d). The district court granted the government's motion, holding that Lone Star had neither established that the FDA owed a duty under Texas law nor raised a fact issue on whether the FDA proximately caused Lone Star's claimed damages. Lone Star now appeals.

II. STANDARD OF REVIEW

"We review a grant of summary judgment *de novo*, applying the same standards as the district court." *Frakes v. Crete Carrier Corp.*, 579 F.3d 426, 429 (5th Cir. 2009). Summary judgment is appropriate when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a

matter of law." Fed. R. Civ. P. 56 (c). Summary judgment is proper only if no reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Where the nonmoving party bears the burden of proof at trial on a dispositive issue, he or she must go beyond the pleadings and designate specific facts showing a genuine issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). Factual controversies are resolved in favor of the nonmoving party, but factual controversies require more than conclusory allegations, unsubstantiated assertions, or a mere scintilla of evidence. *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994).

III. DISCUSSION

The Federal Tort Claims Act, 28 U.S.C. §§ 2671 *et seq.*, abrogates the United States' sovereign immunity for compensatory damages arising out of claims for

> Injury or loss of property . . . caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

28 U.S.C. § 1356 (b) (1); see *Johnson v. Sawyer*, 47 F.3d 716, 727 (5th Cir. 1995) (en banc). The parties agree, and we will assume for purposes of this appeal, that Texas law governs this dispute.[1]

In Texas, the elements of negligence "are the existence of a legal duty, a breach of that duty, and damages proximately caused by the breach." *IHS Cedars Treatment Ctr. Of DeSoto, Tex., Inc. v. Mason*, 143 S.W.3d 794, 798 (Tex. 2004). "The two elements of proximate cause are cause in fact (or substantial factor) and foreseeability." *Id.* The district court concluded that Lone Star had failed to establish the duty of care a private laboratory in these circumstances would owe under Texas law. It further found that Lone Star had failed to present any evidence that the FDA proximately caused its financial loss. Because we find the causation issue dispositive, we do not address the district court's conclusion regarding duty.

The parties agree that Lone Star's summary judgment burden regarding proximate cause is to provide evidence that would allow a reasonable fact finder to conclude that the FDA's negligence caused a false positive result. Our review of the record leads us to the conclusion the district court reached; the summary judgment evidence does not raise a genuine issue of material fact on causation.

Lone Star urges that its evidence permits a reasonable juror to find that the FDA caused the

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[1] We note that Lone Star's claims of negligence related to biscuits the FDA collected in Arizona and tested in California.

biscuits to falsely test positive for *Listeria monocytogenes*. It cites Benware's deposition testimony related to collecting the biscuit samples from MarketFare for the following summary judgment facts: (1) Benware was not aware that the biscuits were in a perforated shrink-wrap packaging and thus might have been contaminated as he and the other inspector reached into the box; (2) the packaged biscuits were not placed in sterile containers for shipment to the FDA laboratory; and (3) the government documents do not establish the chain of custody for the biscuits. Lone Star also claims that the FDA impliedly acknowledged it had contaminated the biscuit samples when it failed to demand a market recall, despite the widespread sales of biscuits to other food sellers.

The government responds that this deposition testimony fails far short of the minimum required to establish causation. It cites the report prepared by Lone Star's expert witness, which concludes:

> The integrity of the biscuit samples collected at MarketFare on March 21, 2002, was compromised by the FDA; thus, all results with regard to the biscuit component were meaningless. The FDA failed to follow its directives and mandates throughout its investigation at MarketFare, which began on March 21, 2002.

The government contends that a mere possibility of contamination differs meaningfully from evidence

that contamination and a false positive in fact occurred. It argues that the former would amount to a strict liability standard for any breach of agency procedures, while the latter is unsupported by the summary judgment evidence.

In support of their arguments on causation, both parties cite the unpublished decision of *Baker v. Abo*, No. Civ. 01-1248, 2003 WL 21639151 (D. Minn. July 2, 2003). In that case, a truck driver was discharged based on the results of a drug test that he argued was improperly performed, leading to contamination of the sample and a false positive result. *Id.* at *1. The truck driver asserted that due to claimed irregularities in conducting the test, his results should have been voided and not communicated to the employer. *Id.* at *2. The court considered an affidavit by the truck driver's expert witness, but found the expert "did not opine that [the breach alleged] could have caused the positive result in this test"; the remaining evidence did not permit a reasonable factfinder to determine the defendant's negligence caused the false positive result. *Id.* at *4. The court expressly rejected a strict liability standard under which a mere possibility of contamination would carry the truck driver's summary judgment burden of raising a fact issue; it then granted summary judgment for the employer, finding the truck driver had failed to raise a fact issue on causation. *Id.* at *3-4.

Our review of the record reveals that the report of Lone Star's expert and the deposition testimony of Benware are the only pieces of

evidence that pertain to the issue of proximate causation. The expert report discusses several instances where the FDA inspectors failed to follow agency collection and testing protocol, but it is devoid of any claim that these failures caused the biscuit samples to test falsely positive for *Listeria monocytogenes*. Benware's testimony similarly permits an inference of breach, but it fails to raise a fact issue on whether the FDA's conduct caused the biscuit samples to test falsely positive for the bacteria. Because Lone Star bore the burden of proof on this essential element of its cause of action, the district court properly granted summary judgment to the government.

IV. CONCLUSION

For the reasons discussed above, the district court's grant of summary judgment for the government is AFFIRMED.

APPENDIX C – ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT DENYING PETITION FOR REHEARING FILED JANUARY 12, 2010

No. 09-50374

LONE STAR BAKERY, INC.,

Plaintiff - Appellant,

v.

UNITED STATE OF AMERICA,

Defendant - Appellee.

Appeal from the United States District Court for the Western District of Texas, San Antonio

ON PETITION FOR REHEARING

Before KING, STEWART, and HAYNES, Circuit Judges.

PER CURIAM:

IT IS ORDERED that the petition for rehearing is denied.

ENTERED FOR THE COURT:

/s/
CAROLYN DINEEN KING
United States Circuit Judge